

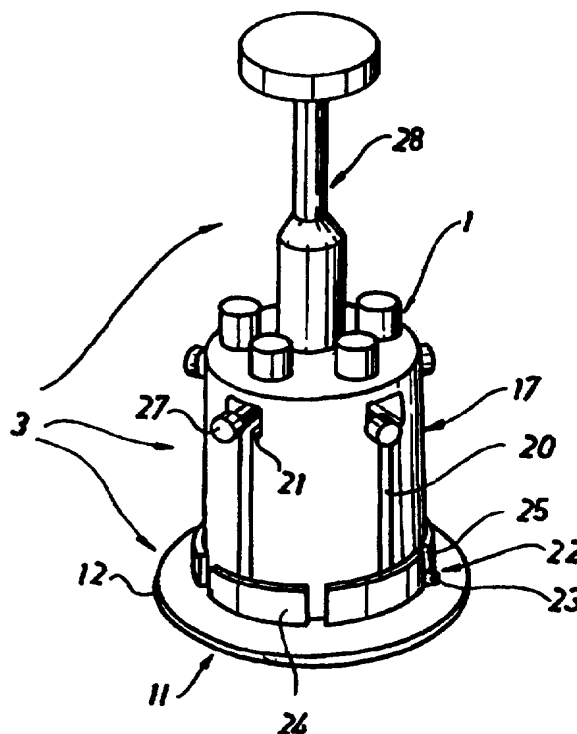
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In English translation (filed in Swedish).***(54) Title:** A DEVICE FOR INTRODUCTION AND/OR WITHDRAWAL OF A MEDIUM INTO/FROM A CONTAINER**(57) Abstract**

The invention concerns a device for introduction and/or withdrawal of a medium into/from an apertured container, and it comprises at least one transfer member (1) for transferring medium to or from the container, and at least one seal. The seal is incorporated as a sealingly mounted part of the transfer member (1) and the transfer member (1) is by means of a fastening device (3), via the seal, sealingly secured to the container aperture during use and then forms a closed system together with the container. The transfer member (1) is removable for replacement thereof after use and the seal has a sealable channel to interconnect the transfer member (1) and the container interior during use.



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A DEVICE FOR INTRODUCTION AND/OR WITHDRAWAL OF A MEDIUM  
INTO/FROM A CONTAINER

The present invention relates generally to a device for introduction and/or withdrawal of a medium into/from a container, and more particularly to such devices for introduction and/or withdrawal of media into/from a  
5 container as are intended for use in areas with very strict requirements on low contamination risks inside the container and/or in the container environment.

Within for instance the pharmaceutical and biotechnology fields and to some extent in the food  
10 manufacturing and cosmetic industries there is a continuous need for sampling of media, for example for micro-biology checks, cell counts, or for chemical analysis, or for addition of regulating or active media, such a pH-buffer of a biological starting culture, during  
15 a certain processing step in the production of products within each field. When such production is carried out under conditions of low contamination requirements with respect to the media that are taking part in the process, the production normally is carried out in a sealed  
20 container. However, contamination risks arise when a medium is to be added to or a sample be withdrawn from the container.

One example of a prior-art device for withdrawing samples from a container for the above mentioned usages  
25 is shown in US-A-3 779 082. The device comprises a self-sealing membrane disposed in an aperture in the container. A plurality of channels interconnect the membrane with the area exteriorly of the container. A transfer member fitted with a hypodermic needle may be  
30 received in one of the channels, it being possible to introduce the hypodermic needle through the membrane into communication with the container interior. In this manner

samples may be withdrawn from the container or a medium be introduced into the container via the hypodermic needle. A vinyl tape or the like covers the upper ends of the channels until the transfer member is inserted into the channels. The device may be pre-sterilised, in which case the channels are not exposed to contamination risks until a transfer member is inserted therein.

A drawback inherent in this construction is that the upper part of the membrane may be contaminated in connection with the transfer member contacting the membrane. Impurities and the like may be drawn into the container via the hypodermic needle. In addition, a small amount of the medium will always accompany the hypodermic needle as the latter is withdrawn from the membrane. In this manner the area exteriorly of the container is exposed to contamination risks when this prior device is in use, which is particularly serious when for instance specimen of toxic media are being withdrawn.

In US-A-3 776 042 is shown another device for withdrawal of samples from a container. This device comprises two self-sealing membrane parts which are sealingly disposed in a hose fitting in a container. An aseptic medium, such as steam or the like, flows from an inlet to an outlet in the hose fitting intermediate the membrane part. The hypodermic needle of a transfer member pierces the outer membrane part and is disinfected by the steam before being introduced into the inner membrane into communication with the container interior. In this position a sample may be withdrawn. When the hypodermic needle is pulled out, it is again sterilised by steam in the area intermediate the membrane parts.

The drawback inherent in this device is that to use steam requires expensive special equipment. Steam may be useful for sterilising against bacteria but this equipment cannot be used for sampling media that must not contaminate the environment and that are not destroyed by steam, since they may accompany the hypodermic needle as

the latter is withdrawn from the two membrane parts or contaminate the area between the membrane parts or the steam tube system connected to the area between the membrane parts. In addition, the sample and the  
5 environment may come into contact with one another via the hypodermic needle tunnel, once the hypodermic needle has been withdrawn from the membrane parts, which in itself constitutes a contamination risk.

On account of the risks of contamination of the  
10 medium inside the container and the container environment, sampling or introducing of media normally are carried out in "clean rooms" by means of devices in accordance with prior-art technology, which involves high investment costs for ventilation equipment, locks and the  
15 like, in addition to which the requirements on the personnel working in the "clean room" are particularly severe.

A first object of the subject invention thus is to provide a device for introduction and/or withdrawal of a  
20 medium into/from a container, according to which the medium upon and following withdrawal is protected from contamination from the environment.

A second object of the present invention is to provide a device for introduction and/or withdrawal of a  
25 medium into/from a container, according to which the environment is protected from contamination from the medium being withdrawn.

A third object of the present invention is to provide a device for introduction and/or withdrawal of a  
30 medium into/from a container, according to which the medium, when being introduced into the container, is protected from contamination from the environment.

A fourth object of the present invention is to provide a device for introduction and/or withdrawal of a  
35 medium into/from a container, according to which the environment is protected from contamination during introduction of a medium into the container.

A fifth object of the present invention is to provide a device for introduction and/or withdrawal of a medium into/from a container, according to which a sample that has been withdrawn from the container, is  
5 representative of the medium inside the container.

A sixth object of the present invention is to provide a device for introduction and/or withdrawal of a medium into/from a container, according to which the device may be used also outside "clean rooms".

10 These and other objects are achieved in accordance with the invention by means of a device for introduction and/or withdrawal of a medium into/from a container as defined in claim 1.

Other particularities and advantageous embodiments  
15 are defined in the dependent claims.

In the following will be described currently preferred embodiments of the present invention in closer detail with reference to the accompanying drawings, wherein:

20 Fig. 1 is a schematical exploded view showing one embodiment of a device for introduction and/or withdrawal of a medium into/from a container.

Fig. 2 illustrates the device of Fig. 1 schematically in its assembled condition.

25 Fig. 3 is a schematical cross-sectional view showing a transfer member with the tip of a hypodermic needle disposed in a protective membrane portion.

Fig. 4 is a schematical cross-sectional view of the transfer member of Fig. 3, according to which the tip of  
30 the hypodermic needle has penetrated the membrane portion.

Fig. 5 is a schematic cross-sectional view illustrating the device when attached to a container.

Fig. 6 is a schematic perspective view, showing an alternative embodiment of a collection receptacle in a  
35 compressed condition.

Fig. 7 is a schematical cross-sectional view of the collection receptacle illustrated in Fig. 6, showing said

receptacle in an expanded position and also showing schematically, by means of a dash-and-dot line, the collection receptacle in its compressed condition.

The device illustrated in Fig. 1 comprises five transfer members each one of which is designated generally by reference 1. In accordance with a preferred embodiment the transfer member 1 is an injector/ejector means. At its lower end each transfer member is formed with a seal, generally designated by reference 2. In addition, the device comprises a fastening device, generally designated by 3, which device consists of three parts.

Each transfer member 1 is provided with a holder 4. The holder encloses the upper end of a hypodermic needle 5. The lower edge of the holder 4 is formed with a downwardly open groove 6 having an essentially circular cross-sectional configuration.

The seal 2 is formed with an upper bellows-shaped part 7. At its upper end the bellows-shaped part 7 is formed with a bead 8 which is inserted in the groove 6, thus sealingly interconnecting the seal 2 and the holder 4. The bellows-shaped part 7 encloses the hypodermic needle 5 in the longitudinal direction thereof and it may be compressed in the lengthwise direction of the needle 5 between the positions illustrated in Figs 3 and 4, respectively. At its lower end the seal 2 is formed with a membrane portion 9 the upper end of which is sealingly attached to the bellows-shaped part 7. The membrane portion 9 is self-sealing and is pierceable by the tip 10 of the hypodermic needle.

The fastening device 3 comprises one flanged part, generally designated by reference 11. The flanged part 11 is formed with an essentially circular base plate 12 in which five through holes 13 are made, each having a diameter-size allowing passage therethrough of a hypodermic needle 5. About each hole 13, in the upper face of the base plate 12, is formed a seat 14, said seat

being essentially centered about the hole 13. The lower end of the membrane portion 9 is formed with a collar 15 fitting the seat 14. From the upper face of the flanged part 11, projecting essentially perpendicularly therefrom, is arranged a stub axle 16 having a threaded upper end.

The fastening device 3 likewise comprises an essentially cylindrical magazine part, generally designated by 17. A centrally located, longitudinal through channel 18 passes through the magazine part 17, through which channel the stub axle 16 may project. In addition, the magazine part 17 is formed with five through apertures 19 extending in parallel with channel 18 and having a diameter-size corresponding to or slightly exceeding the diameter-sizes of the holder 4, the bellows-shaped part 7, and the upper end of the membrane portion 9 but being smaller than the diameter of the collar 15. The lower end of each aperture 19 is connected to a longitudinal outwardly open groove 20 provided in the peripheral surface of the magazine part 17 exteriorly of the associated aperture 19. At its upper end, the groove 20 is formed with two lateral recesses 21.

The magazine part 17 and the flanged part 11 have a centering means generally designated by 22 (see Fig. 2). The centering means 22 comprises at least one pin 23 projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part 17. The flanged part 11 is formed on its upper face with an annular means 24 matching the cross-sectional area of the magazine part 17 so as to fit the exterior of the latter. The annular means 24 is formed with at least one slit 25 into which the pin 23 may be inserted.

The upper end of the hypodermic needle 5 is sealingly connected to a hose socket or fitting 26 which is receivable in the groove 20. The hose socket 26 may be formed with a peripheral stop shoulder 27 (see Fig. 1)



alternatively, the hose socket 26 may in itself function as a stop shoulder (see Figs 3 and 4). In Figs 1 and 2 the stop shoulder 27 has a larger diameter-size than the groove 20 and is spaced such a distance from the holder 4 that the transfer member 1 may be introduced into the aperture 19 and the groove 20 from the lower end of the magazine part 17.

In addition, fastening device 3 comprises a locking part, generally designated by 28, said locking part being formed at its upper end with a knob 29 and at its lower end with a threaded bore (not shown) into which the stub axle 16 may be screwed.

The stub axle 16, the channel 18, and the locking part 28 together form a device fastening means, generally designated by reference 30.

The hose socket 26 is sealingly connected to a collection receptacle, generally designated by 31, preferably by means of a hose 32. The collection receptacle 31, shown in a cross-sectional view in Fig. 5, has a bottom portion 33 and a top portion 34 which are sealingly interconnected. The bottom portion 33 is manufactured from a stiffer material than the top portion 4. The top portion 34 is formed with an essentially centered handle 40 on its exterior and may be formed with folding initiation means 35 on its surface, essentially centered about the handle 40. The collection receptacle 31 is expandable into the configuration illustrated by the right-hand receptacle in Fig. 5, and compressible into the configuration shown by the left-hand collection receptacles in Fig. 5. The expansion and compression, may if required, be facilitated by the folding initiation means 35. However, such means are not a precondition for the function of the collection receptacle 31.

The operation of the device will appear from the description to follow. The flanged part 11 is associated with a container, generally designated by 36, via an aperture 37 therein. The flanged part 11 is secured in

the aperture 37 in such a manner that it seals the edges of the aperture 37. In this position the holes 13 set the interior of the container 36 in communication with the environment. Initially, the container is empty (not  
5 shown) and it is of the type used in processes requiring containers that may be sealed off against the environment.

Five unused transfer members 11 are inserted into the magazine part 17 from underneath. The stop shoulders  
10 27 are then turned laterally into locking engagement with a lateral recess 21 (see Fig. 2). When a transfer member 1 assumes its inserted position its collar 15 abuts against the lower portion of the magazine part 17. The upper portion of the holder 4 projects through the upper  
15 portion of the magazine part 17. In this starting position each hypodermic needle 5 is sealingly introduced into the membrane portion 9 to assume the position illustrated in Fig. 3. The magazine part 17 is then slid over the stub axle 16. The annular means 24, the pin 23  
20 and the slit 25 co-operate to center the magazine part 17 in such a manner that the hypodermic needle 5 of each transfer member 1 will be positioned straight above a corresponding hole 13. The collar 15 of each transfer member 1 fits the corresponding seat 14. The locking part  
25 28 is then screwed onto the stub axle 16, whereby the magazine part 17 is locked in the position illustrated in Fig. 2. In this locked position the material of the self-sealing collar 15 is compressed, exerting a sealing pressing action against the seat 14, whereby the holes 13  
30 will be sealed against the environment.

The hypodermic needle 5, the hose 32 and the collection receptacle 31 form a unit that is sealed against the environment as long as the hypodermic needle 5 remains in the position illustrated in Fig. 3. The unit  
35 preferably is pre-sterilised. At their upper ends the collection receptacles 31 are formed with an aperture by

means of which the receptacles may be suspended from hook means 38 on the container 36.

After the device thus having been secured to the container 36 in the manner described, the interior of the container 36 may be cleansed and sterilised in any known manner. During this procedure the inner face of the flanged part 11, the holes 13 and the lower part of the membrane portion 9 in contact with the interior of the tank are cleaned. All components of the device that come into contact with the interior of the container 36 thus will achieve the same degree of purity as the interior of the container 36, whereby the risks of contamination from these components are eliminated.

The container 36 is thereafter filled with a medium 39 to a level above the aperture 37 and the process inside the container may be initiated. When samples are to be withdrawn from the container 36 the stop shoulder 27 of one of the transfer members 1 is turned to dislodge it from its locking engagement with a lateral recess 21. The stop shoulder 27 is then displaced, and consequently also the hypodermic needle 5 and the bellows-shaped part 7, in the lengthwise direction of the groove 20 and the aperture 19, to the position illustrated in Figs 4 and 5 by reference 41, wherein the tip 10 of the hypodermic needle 5 has penetrated the membrane portion 9. In this position, the collection receptacle 31 is in sealed communication with the interior of the container 36. Since the tip 10 of the hypodermic needle 5 is pre-sterilised no contamination has arisen from this movement.

Owing to the hydrostatic pressure caused by the level differences between the medium inside the container 36 and the collection receptacle 31, the medium 39 may in position 41 illustrated in Fig. 5 flow through the hypodermic needle 5, through the hose 32 to be collected in the collection receptacle 31. As the container 31 is being filled, it expands, and this expansion is

facilitated by the above-mention folding initiation means 35. In order to speed up the filling operation the collection receptacle 31 may initially be expanded manually with the aid of the handle 40, causing a vacuum pressure to generate in the collection receptacle 31.

When a sufficient amount of the medium 39 has been withdrawn from the container 36, the transfer member 1 is retracted to the position illustrated in Figs 3 and 5 by reference 42 and it is locked in that position through the engagement of the stop shoulder 27 in the a lateral recess 21. This seals the channel formed by the needle 5 inside the membrane portion 9, whereby the tip 10 of the hypodermic needle 5 will be sealed inside the membrane portion 9. Since the hypodermic needle 5, the hose 32 and the collection receptacle 31 again form a closed, sealed system contamination of the withdrawn sample or contamination of the environment outside the container 36 are prevented. Owing to the lower collar 15 of the membrane portion 9 being pressed against the seat 14 of the fastening means 30 the sealing effect between these parts is improved, in addition to which the self-sealing capacity of the membrane portion 9 is increased.

The hose 32 leading to a filled collection receptacle 31 may thereafter be sealingly cut off by a cutter means (not shown), whereupon the collection receptacle 31 may be transported to a laboratory or the like while still all contamination risks are avoided. The cutting means could for example be a device of the kind that fuses together the two hose ends, or it could be a device which sealingly squeezes together the hose ends by means of clamps.

Five samples may be withdrawn by the device in accordance with the shown embodiment. The number of devices for a container 36 as well as the number of transfer members 1 for each device could, however, differ.

When the process in the container 36 has come to an end, the container is emptied, cleansed and disinfected from within. During this operation the components of the device that are exposed to the tank interior are  
5 cleansed. The locking part 28 may then be released and the magazine part 17 be pulled off from the stub axle 16 without risks of contaminating the environment. The entire magazine part 17 may then be exchanged for a new magazine part 17 that is loaded with unused transfer  
10 members 1. Alternatively, it is possible to replace used transfer members 1 in one and the same magazine part 17. As long as used hypodermic needles 5 are not pulled out of the membrane portion 9 the hypodermic needle 5 and the corresponding cut-off hose end form a closed, sealed  
15 system. Used hypodermic needles, hose parts and collection receptacles are destructed in a manner suitable considering the medium, for instance by incineration. The parts of the device which after use are to be destructed preferably are incinerated, since these  
20 parts as such are manufactured from a combustible material that does not emit noxious fumes. The magazine part 17 is then locked in the position as indicated above and the interior of the container 36 is cleaned and disinfected preparatory to a new process step.

25 The hose 32 of a filled collection receptacle 31 obviously need not be cut off for transportation of the sample when the magazine part 17 is removed from the container 36. Instead, the transfer member 1 may be removed from the magazine part 17, and the transfer  
30 member 1, the hose 32, and the collection receptacle 31 be transported to a laboratory or the like. Alternatively, the hose 32 may be directly connected to analysis equipment, to another container or the like.

35 It is not either necessary to remove the magazine part 17 and the transfer member 1 each time the container 36 is emptied and cleaned, since the parts of the device that are exposed to the interior of the container 36 are

imparted the same degree of purity as the container interior upon cleaning and disinfection thereof. Consequently, the device may be used in several processing steps without being removed, as long as the  
5 number of unused transfer members 1 is sufficiently large.

A second hose may be sealingly connected to the collection receptacle 31 or to the hose 32. At the end of the second hose a pre-sterilised syringe may be sealingly  
10 attached for transfer of the specimen to another container or the like. Furthermore, the second hose may be connected to a second transfer member 1. In this manner, the medium 39 may be withdrawn from a container 36 in a sealed condition and be introduced into a second  
15 container (not shown) in sealed condition by means of a device as described above. In this case a hypodermic needle 10 is introduced into the second container, whereupon the collection receptacle 31 is positioned above the level of the medium in the second container,  
20 whereupon the medium in sealed condition may be introduced into the container by means of the hydrostatic pressure. In order to facilitate the introduction of the medium the deformable upper portion 34 of the collection receptacle 31 may be compressed against the bottom  
25 portion 33.

Figs 6-7 illustrate a second embodiment of a collection receptacle 31'. Parts similar to those described with reference to Figs 1-5 have received the same references in Figs 6-7 but with the addition of a  
30 prime sign. The collection receptacle 31' comprises a first essentially arch-shaped part 33' and a second essentially arch-shaped flexible part 34'. In accordance with the embodiment illustrated the parts 33' and 34' are essentially domed and preferably are manufactured from a  
35 plastics material, the first part 33' preferably being manufactured from a material possessing a higher degree of rigidity than material of the second flexible part

34'. In Fig. 7 continuous lines illustrate the collection receptacle 34' in an expanded position in which it is filled with medium 39' whereas dash-and-dot-lines illustrate the receptacle in its compressed position. In the compressed position the second flexible part 34' is disposed adjacent the first part 33' to allow a collection receptacle 31' to be completely emptied of medium 39' that has collected therein. As appears from Figs 6-7 a handle 40' is provided on the second flexible part 34' to facilitate handling of the second flexible part 34' between the expanded position and the compressed position. However, it is easily understood that it is likewise possible to realise the shift from one position to the other in some other way, for example by making use of the hydrostatic pressure like in the first embodiment above.

The first part 33' and the second flexible part 34' are interconnected in an interconnection area 50 along a facing marginal portions of the parts. The joint or interconnection between the parts 33'-34' may be made for instance by gluing or welding. As appears from Fig. 7 the interconnection area 50 in accordance with the shown preferred embodiment extends essentially in parallel with the extension of the marginal areas of the second flexible part 34' in the expanded position. Owing to this arrangement the risk of bursting of the second flexible part 34' in the interconnection area 30' is reduced as is also the risk of tearing in the connection area 50 as the collection receptacle 51 is exposed to an excess pressure, e.g. in comparison with a structure wherein an interconnection area between the first and the second parts extends horizontally with respect to Fig. 7 (not shown).

Externally of its dome the first part 33' preferably is formed with an annular collar or flange 51 which extends along said interconnection area 50 and which is connected to the second flexible part 34' by being joined

thereto in the interconnection area 50. The collar 51 and the first part 33' are interconnected in accordance with the shown embodiment along a peaked rim 52 bent at a preferably acute angle  $\alpha$ , across which rim the second flexible part 34' may be shifted between the compressed position and the expanded position. Preferably, the interconnection area 50 extends exteriorly of said peaked rim 52. The rim 52 consequently acts as a "hinge" across which the second flexible part 34' moves between the expanded and the compressed positions. When the interconnection area 50 extends beyond said peaked rim 52, as is the case in accordance with the preferred embodiment, the "hinge" movement affects the interconnection area 50 less as this second flexible part 34' moves, as compared with what would be the case, had said interconnection for instance extended up to or terminated interiorly of said marginal area 50. The movement of the second flexible part 34 thus is effected in accordance with the embodiment in an area which is disposed interiorly of the interconnection area 50, imparting higher strength to the interconnection between the first part 33' and the second flexible part 34'.

As illustrated in Fig. 6 the collection receptacle 31' is formed with at least one channel 53 which in accordance with the embodiment shown extends through said interconnection area 50 and which in accordance with the shown embodiment is connected to a hose 32', the latter in turn being connected to a hypodermic needle disposed in a transfer member 1' of similar construction to that described above and which has a holder 4' and a seal means 2'. In this manner, the collection receptacle 31' thus is connected to the hypodermic needle of the transfer member 1'. In accordance with the shown embodiment the channel 53 is likewise by means of a second hose 54 connected to a hypodermic needle 55 known per se, which is provided in a close-fitting removable cover 56. A clamping device 57 known per se is arranged



about the second hose 54 in accordance with the shown embodiment. The entire unit illustrated in Fig. 6 is preferably pre-sterilised and preferably forms a sealed unit prior to use.

5       The collection receptacle 31' and accessories are shown in Fig. 6 in a transportation position wherein the hoses 32' and 54 are disposed underneath flaps 58 and 59, respectively fastened by snap fasteners. The clamping device 57 and/or the hoses 32' and 54, respectively,  
10       and/or the transfer member 1 preferably are disposed in depressed parts in a holder 62 located around the collection receptacle 31' in order to provide improved stackability of the collection receptacle 31'. In accordance with the shown preferred embodiment the holder  
15       62 is a continuation of the first part 33'. Consequently, for instance the hoses 32' and 54 may be disposed in the position of transportation in grooves 60 and 61, respectively, as seen in Fig. 7. Also the clamping device 57 is illustrated in Fig. 6 in a depressed position in  
20       the holder 62.

As appears from Fig. 6 the second flexible part 34' is formed in accordance with the shown embodiment with a portion 63 which for instance by welding or gluing is interconnected with the holder adjacent the channel 53  
25       and the area of interconnection of the channel 53 with the respective hose 32', 54 to allow sealing interconnection of the respective hose 32', 54 with the collection receptacle 31'.

It is easily understood that via the collection  
30       receptacle 31' and a hypodermic needle arrangement 55, 56, 57 and/or directly, the transfer member 1' may be connected to another container, another collection vessel, analysis equipment, or some other form of receptacle, etcetera.

35       By the inventive construction a device is provided according to which the introduced and/or withdrawn medium is protected from contamination from the environment of

the container 36. In addition a device is provided protecting the environment from the withdrawn and/or introduced medium. Owing to this device a representative specimen may be withdrawn from the container without involving or causing contamination risks. Because the device, when correctly used, eliminates contamination risks in the container and in its environment, the container may be disposed in an ordinary room with no particular strict requirements on cleanliness. Because a

5       collars 15 of the different transfer members 1 are separate from one another upon sampling or introduction of medium into the container 36 there is no risk of cross-contamination between a first collar 15 and a second collar 15. Because it is clearly apparent from a

10       filled collection receptacle 31; 31' or from a cut-off hose 32; 32'; 54 that the corresponding transfer member 1; 1' has been used the risk that a hypodermic needle 5 would be used twice by mistake is very small, which, had it occurred, could have involved a contamination risk.

15       Because the hypodermic needle 5, the hose 32; 32', and the collection receptacle 31; 31' form a pre-sterilised sealed unit and because the parts of the device that are exposed to the container interior are cleansed and disinfected simultaneously with the cleaning and the

20       disinfection of the container, the device has a contamination level corresponding to that of the container interior. Because the point on the hose 32; 32' where the cut is effected is sealed the joint can never contaminate the environment.

25       It is easily understood that certain deviations from the described embodiment may be made. For instance the number of parts and the configuration of the fastening device 3 may be varied. In addition, the hose 32; 32' could for instance be a tube. The grooves 20 may run

30       along the entire outer face of the magazine part 17 and a stop/locking device be arranged in the locking part 28, the function of which corresponds to that of the stop

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means and the locking means in the upper part of the groove 20 and the lateral recesses 21. The container 36 obviously could be in the form of a tank, a tube pipe or other type of vessel. All such of varieties and  
5 modifications that are encompassed by the basic inventive concept should be regarded to be within the scope of the appended claims.

CLAIMS

1. A device for introduction and/or withdrawal of a  
5 medium (39) into/from a container (36) having an aperture  
(37) formed therein, said device comprising at least one  
transfer member (1) for transferring medium (39) into or  
withdrawal of medium from the container (36), and at  
least one seal (2), c h a r a c t e r i z e d in that the  
10 seal (2) is included as a sealingly mounted part of the  
transfer member (1), in that by means of a fastening  
device (3) the transfer member (1) is via the seal (2),  
sealingly secured in the aperture (37) of the container  
(36) during use of the device (3), during which use it  
15 forms a closed system together with the container (36)  
whereas the transfer member (1) is removable for  
replacement thereof after use, and in that the seal (2)  
is formed with a sealable channel for interconnecting the  
transfer member (1) with the interior of the container  
20 (36) during use.

2. A device as claimed in claim 1, c h a r a c -  
t e r i z e d in that the transfer member (1) is formed  
with a hypodermic needle (5) and in that the seal (2) is  
self-sealing and pierceable by the tip (10) of the  
25 hypodermic needle (5) to produce said sealable channel.

3. A device as claimed in claim 2, c h a r a c -  
t e r i z e d in that the transfer member (1) has a  
holder (4) supporting the hypodermic needle (5), that the  
seal (2) comprises a bellows-shaped part (7) which is  
30 deformable in the longitudinal direction of the needle,  
said bellows-shaped part (7) surrounding the hypodermic  
needle (5) and being attached to the holder (4), and in  
that the seal (2) is formed at its lower end with a  
membrane portion (9) which is pierceable by the tip (10)  
35 of the needle (5) and which is connected to the bellows-  
shaped part (7) and in use of the device seals said  
aperture (37).

4. A device as claimed in claim 3, c h a r a c -  
t e r i z e d in that the fastening device (30) comprises  
a flanged part (11) which is sealingly secured in the  
aperture (37) and is formed with at least one hole (13)  
5 therethrough, a magazine part (17) for removable  
securement of at least one transfer member (1), and a  
fastening means (30) and a centering means (22) for  
removable locking of the magazine part (17) to the  
flanged part (11) in the position wherein the membrane  
10 portion (9) sealingly abuts against the hole (13) and  
wherein the hypodermic needle (5) may be introduced into  
and be withdrawn from the container (36) through the  
membrane portion (9) and the hole (13).

5. A device as claimed in claim 4, c h a r a c -  
15 t e r i z e d in that the fastening device (30) comprises  
a stub axle (16) which is attached to the flanged part  
(11) and projects from the container (36), a channel (18)  
in a magazine part (17) through which the stub axle (16)  
extends in the locked position of the magazine part (17),  
20 and a locking part (28) which in the locked position is  
attached to the stub axle (16) to securely interconnect  
the magazine part (17) and the flanged part (11).

6. A device as claimed in claim 5, c h a r a c -  
t e r i z e d in that the membrane portion (9) is formed  
25 with a bottom collar (5) which in the locked position is  
clamped between the flanged part (11) and the magazine  
part (17).

7. A device as claimed in claim 6, c h a r a c -  
t e r i z e d in that the transfer member (1) is formed  
30 with a stop shoulder (27) adjacent the holder (4), that  
the magazine part (17) is formed with at least one  
longitudinally extending aperture (19) which by means of  
a groove (20) opens towards the lower part of the  
peripheral surface of the magazine part (17), and in that  
35 the upper end of the groove (20) the latter is formed  
with at least one lateral recess (21), said transfer  
member (1) and the stop shoulder (27) in the locked

position of the magazine part (17) being movable in the aperture (19) and in the groove (20) in the longitudinal direction of the hypodermic needle (5), between a first position, in which the needle (5) is in communication  
5 with the interior of the container (36) and a second position, in which the stop shoulder (27) is disposed in the upper end of the groove (20) and in which the tip (10) of the hypodermic needle (5) is sealingly disposed inside the membrane portion (9), said stop shoulder (27)  
10 arranged, in said second position, to be displaced in response to a turning movement, into engagement with a lateral recess (21) to lock the transfer member (1) in said position.

8. A device as claimed in any one of claims 2-7,  
15 c h a r a c t e r i z e d in that the hypodermic needle (5) is sealingly connected to a collection receptacle (31; 31'), said collection receptacle (31; 31') being expandable upon withdrawal of medium (39; 39') from the container (36) and compressible upon introduction of  
20 medium (39) into the container (36).

9. A device as claimed in claim 8, c h a r a c -  
t e r i z e d in that the collection receptacle (31; 31') is connected to the hypodermic needle (5) via a hose (32; 32'), and in that a cutting device is provided to  
25 sealingly cut said hose (32; 32') in order to free the collection receptacle (31; 31') from the hypodermic needle (5).

10. A device as claimed in claim 8 or 9, c h a r -  
a c t e r i z e d in that the collection receptacle (31;  
30 31') has a first part (33; 33') and a second flexible part (34; 34'), and in that a handle (40; 40') is arranged in said flexible part (34; 34'), allowing a vacuum to be produced in the collection receptacle (31; 31') upon pulling on the handle (40; 40') as said  
35 receptacle is being expanded during withdrawal of medium (39).

11. A device as claimed in any one of claims 8-10, characterized in that the collection receptacle (31; 31') has a first essentially domed part (33') and a second flexible and essentially domed part (34'), said parts (33', 34') being interconnected along facing marginal areas in an interconnection area (50), that the second flexible part (34') is movable between a first compressed position in which it bulges into the first part (33') and a second expanded position in which it bulges outwards from the first part (33').

12. A device as claimed in claim 11, characterized in that the first part (33') and the second flexible part (34') are arranged, in said first compressed position, to assume a position closely adjacent one another to allow the collection receptacle (31') to be emptied of substantially all medium.

13. A device as claimed in claim 11 or 12, characterized in that in the expanded position, the interconnection area (50) extends essentially in parallel with the extension of the marginal area of the second flexible part (34').

14. A device as claimed in any one of claims 11-13, characterized in that said first part (33') is formed exteriorly of its dome shape with a collar (51) extending along said interconnection area (50) and being connected to said second, flexible part (34').

15. A device as claimed in claim 14, characterized in that said collar (51) and said first part (33') are interconnected along a peaked rim (42) which is bent at an angle ( $\alpha$ ), preferably an acute angle, across which rim (52) the second, flexible portion (34') is moveable between the first compressed position and the second expanded position, and in that the interconnection area (50) extends exteriorly of said rim (52).

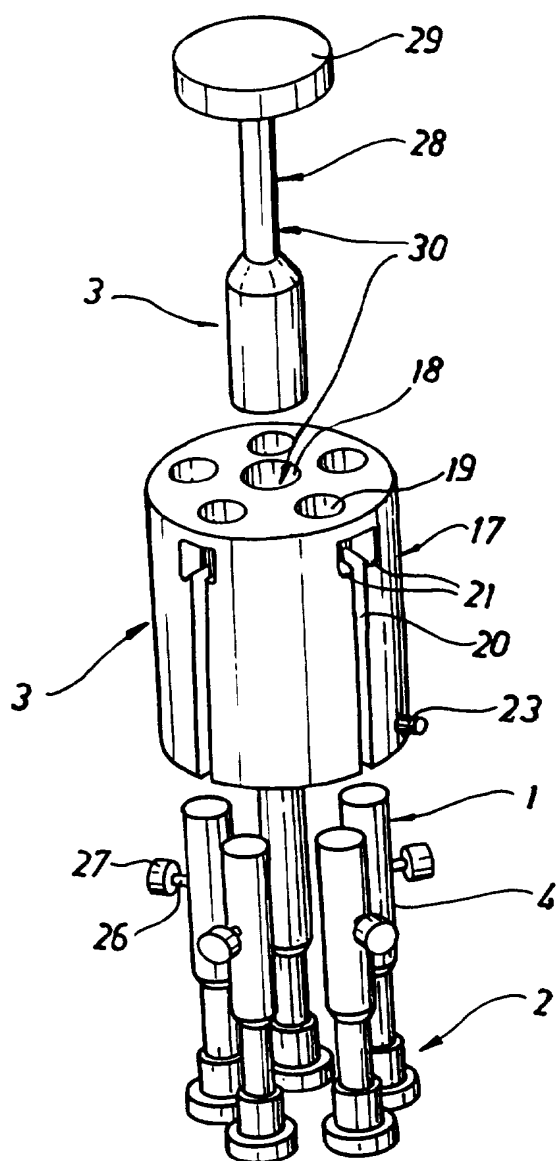
16. A device as claimed in claims 11-15, characterized in that the collection receptacle (31')

is formed with a channel (53) which extends through said interconnection area (50).

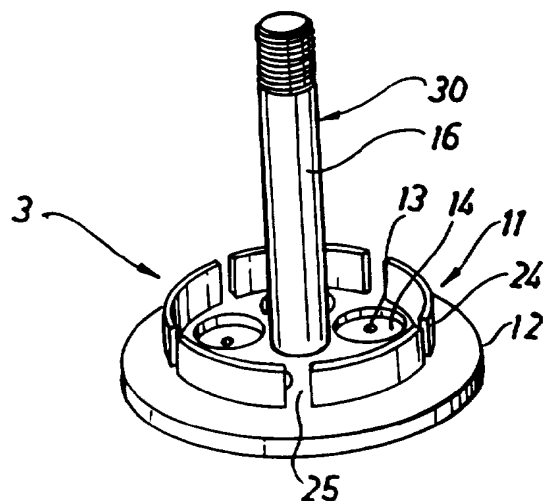
17. A device as claimed in claim 16, c h a r a c -  
t e r i z e d in that said channel (53) is connectable,  
5 for instance by means of a second hose (54) or a pipe to  
a second container, to another collection receptacle, to  
analysis equipment and/or the above hose (32; 32').

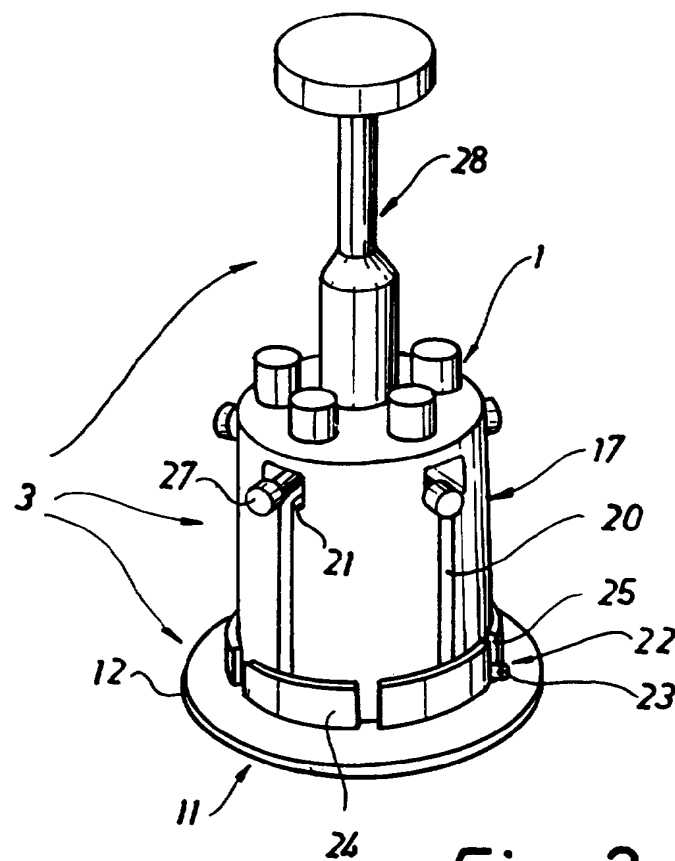


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*Fig. 1*





*Fig. 2*

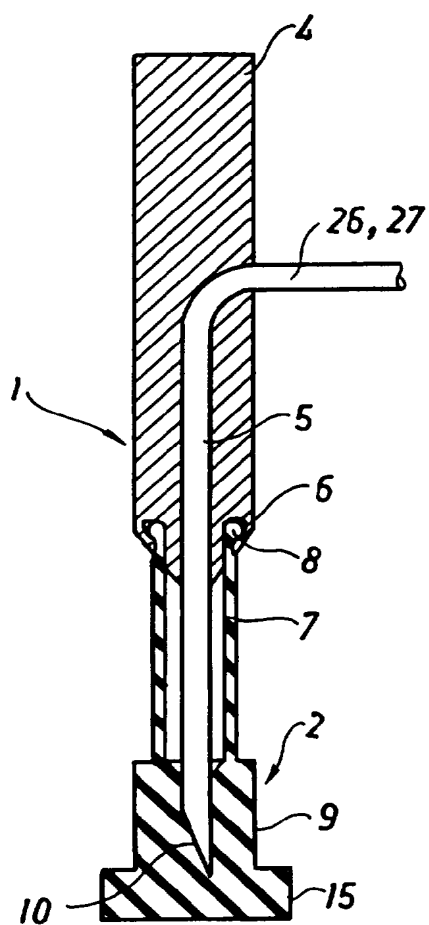


Fig. 3

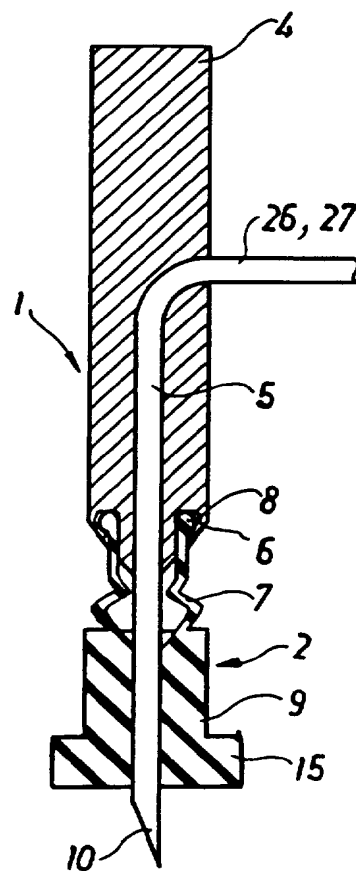
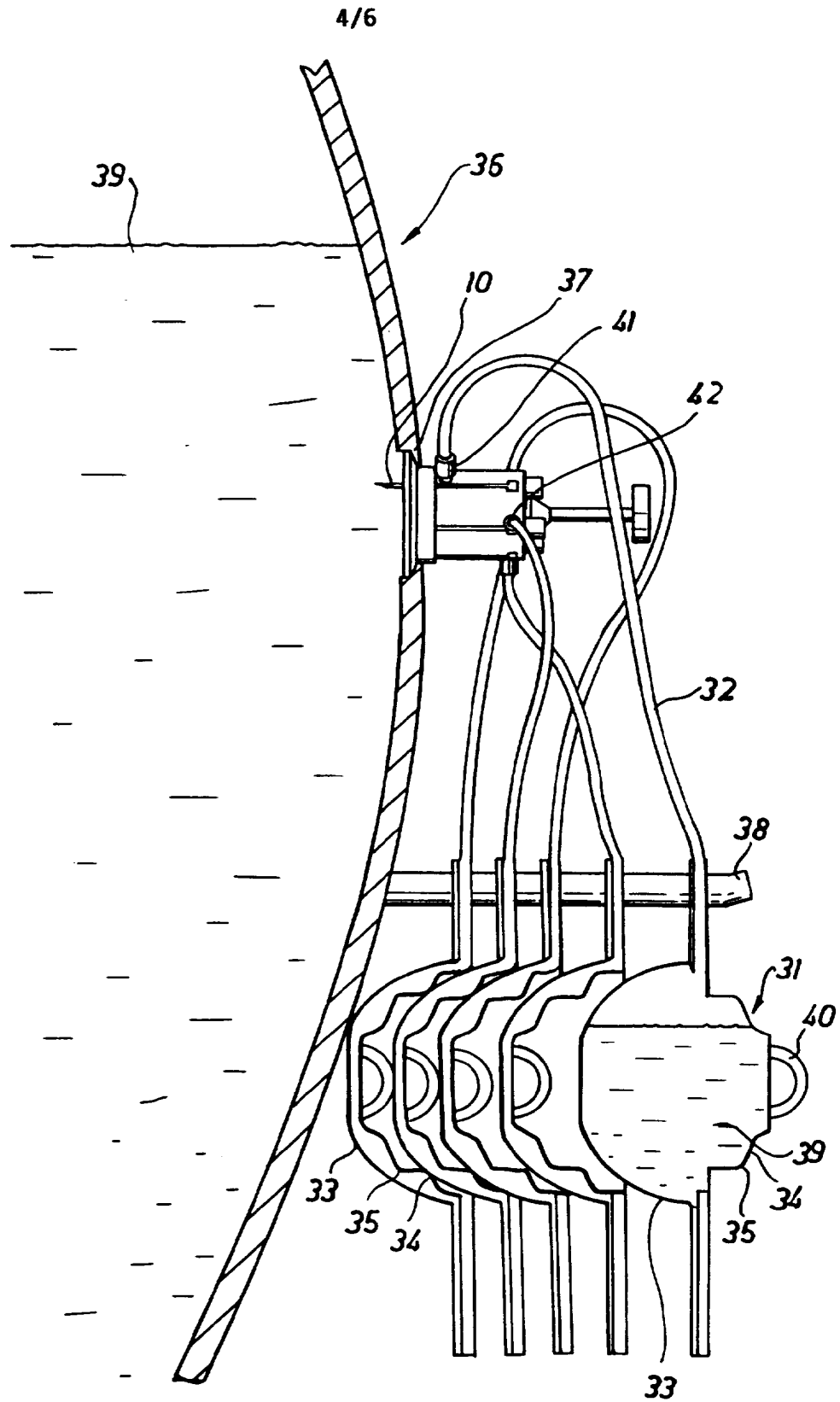
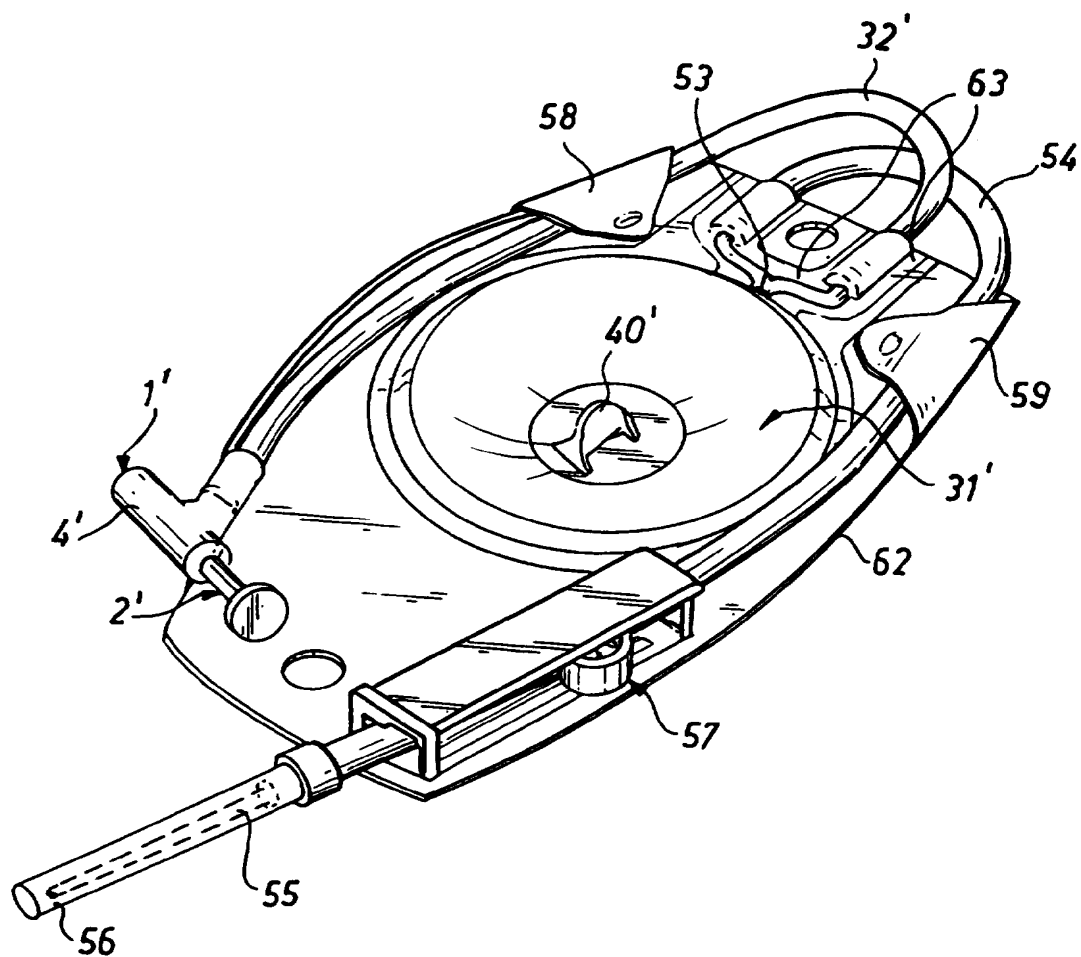


Fig. 4

*Fig. 5*

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*Fig. 6*

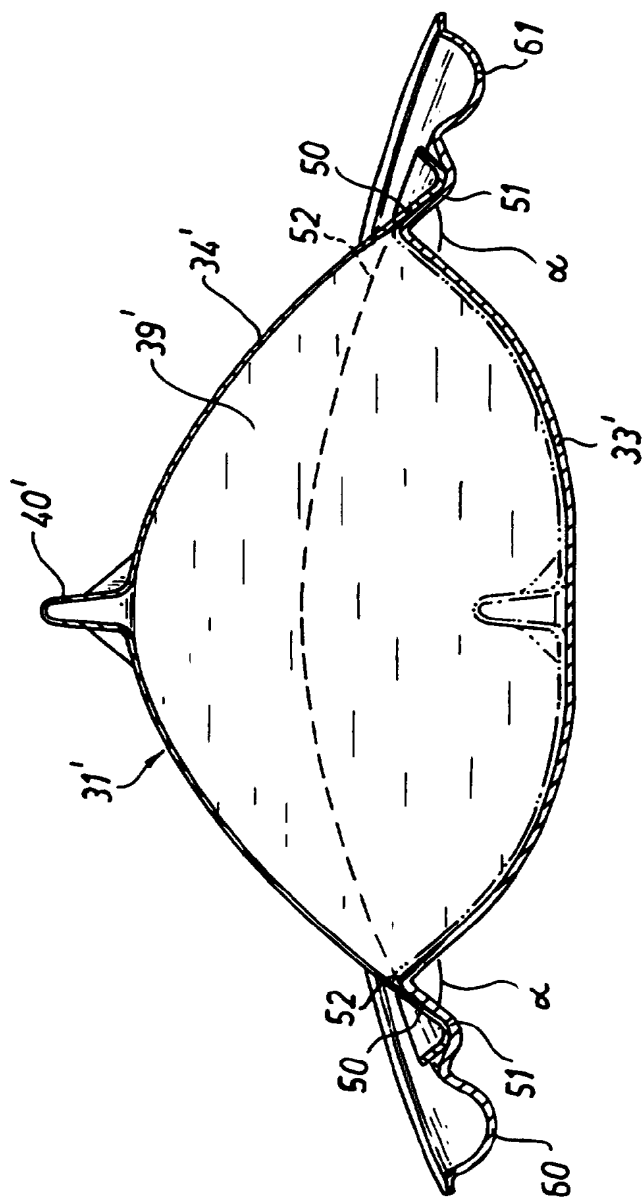


Fig. 7

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 96/01325

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC6: G01N 1/10, G01N 1/38 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: G01N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3779082 A (EDWIN J. GALLOWAY), 18 December 1973 (18.12.73), column 3, line 3 - line 11; column 3, line 53 - column 4, line 2  --	1
X	US 3776042 A (BRUNO H. WERRA ET AL), 4 December 1973 (04.12.73), column 2, line 40 - line 49; column 3, line 15 - line 28  -- -----	1
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
22 January 1997		03 -02- 1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer  Ulla Granlund Telephone No. +46 8 782 25 00

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

28/10/96

International application No.

PCT/SE 96/01325

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US-A-	3779082	18/12/73	CA-A-	975401	30/09/75
US-A-	3776042	04/12/73	NONE		